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PSNC Briefing 007/23: Regulatory easements to seek to reduce costs and bureaucracy and ensure patient safety

Alongside discussions with the Department of Health and Social Care (DHSC) and NHS England (NHSE) on funding for Year 5 of the Community Pharmacy Contractual Framework (CPCF), PSNC has repeated its urgent request for DHSC and NHSE to agree to regulatory changes which would help pharmacy owners to cope with the unrelenting financial and operational challenges they are facing.

Regulatory easements have been under discussion for many months but in February 2023 PSNC rejected proposals from NHSE as being inadequate.

The situation is rapidly deteriorating, so we have now asked for a range of measures to help all community pharmacies to reduce costs and bureaucracy and have the flexibility to manage their pharmacies. We have outlined our proposals below.

Major regulatory easements

Reducing Core opening hours - permanently

CPCF funding no longer supports the number of opening hours provided by the sector, so PSNC wants to enable all pharmacies to seek to reduce costs and only open at times when most patients and the public use the pharmacy.

Proposal: *A pharmacy to be able to:*

- *notify a reduction in core opening hours by 30% while remaining open on usual opening days (with 5 weeks' notice); and*
- *apply to amend core opening hours to fit business needs (provided that patient needs remain met).*

Notices on the pharmacy premises would be required to inform patients of the planned changes to opening hours.

Reducing Core opening hours - temporary

We also want to ensure that a pharmacy can seek to rely on permanent staff and manage the additional costs of locum pharmacists.

Proposal: *A pharmacy to be able to reduce core opening hours on a temporary basis (with 5 weeks' notice), to the extent of closing for one day each week or equivalent reduced hours during the week.*

Notices on the pharmacy premises would be required to inform patients of the planned changes to opening hours.

Closed door working

To help mitigate concerns around meeting increased dispensing volumes and maintaining patient safety, we want to provide support for pharmacies where there are temporary or permanent closures of other nearby pharmacies.

Proposal: *A pharmacy to have the option of closed door working, for an unlimited number of hours; notified to NHSE afterwards, within one week, with the reason for the closed door working.*

These pharmacies should also be able to claim an advance payment to enable the business to manage the associated cash flow issue.

Refusal to provide drugs or appliances to ensure patient safety

In circumstances such as where temporary or permanent closure of a local pharmacy results in sudden, increased demand, contractors must be protected from having to manage workloads that are beyond the capability of pharmacy professionals, the pharmacy team or the pharmacy premises.

Proposal: *A pharmacy to be able to refuse to dispense one or more prescriptions if the prescription volume, or provision of other pharmaceutical services, is such that dispensing could result in professional standards that are below those generally accepted in the pharmaceutical profession, that would raise patient safety concerns.*

Some controls would be added to ensure that this is only used in appropriate circumstances.

Refusal to provide/supply - ensuring reimbursement for medicines for each pharmacy

Individual pharmacies/contractors should not lose money purchasing medicines and medical devices for NHS supply. PSNC wants to ensure that individual contractors are genuinely reimbursed for the cost of a medicine dispensed and an appropriate concession price can be granted.

Proposal: *A pharmacy to be able to delay dispensing if reimbursement is inadequate: where the reimbursement price of a medicine or medical device, in the Drug Tariff, or as a concession price, is lower than the purchase price to the contractor, the requirement to supply with reasonable promptness is replaced by a requirement to supply in a reasonable timeframe (this to be when the reimbursement price from DHSC is equal to or more than the purchase price).*

Margin, part of pharmacy remuneration, remains assessed for the sector as a whole in the usual way.

Moratorium on the opening of new Distance Selling Premises (DSP) pharmacies for 2 years

The grant of the DSP contract for local dispensing undermines the integrity of the current market entry system in the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, which includes other contract types that provide patients and the public with a 'front door' to the NHS on the High Street. We therefore must limit further establishment of DSPs where the application process more or less guarantees the granting of a contract and where the vast majority of DSPs dispense medicines locally and not across the nation, as intended.

Proposal: *DHSC to stop, for at least 2 years, any new applications for DSPs and undertake tripartite work – DHSC, NHSE and PSNC – to reduce the apparent inadequacy of the current regulations/why a contract intended for national supply is increasingly used as an alternative to local supply that subverts a key purpose of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.*

Hub and spoke between different legal entities

We want to stop the proliferation of supply from spokes or hubs that are not NHS pharmacies. The aim is supply of NHS dispensed medicines from NHS pharmacies to ensure the availability of advice from a pharmacist, the safety of medicines stored in a community setting, and the integrity of the market entry system.

Proposal: *DHSC to limit the introduction of hub and spoke dispensing between different legal entities to model 1 in the DHSC consultation document – in essence, supply of NHS medicines to patients to be only from a spoke that is a retail pharmacy business pharmacy premises that has an NHS contract – the premises (address) is on a pharmaceutical list under the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.*

No Pharmacy Quality Scheme (PQS) in 2023/24

There is no capacity for PQS, and Essential services (including dispensing) are underfunded and need support.

Proposal: *DHSC to stop PQS for the year 2023/24.*

Serious Shortage Protocols (SSPs)

SSPs are too complex. Less than 50% of SSPs are claimed successfully and contractors claim relatively few SSPs, which suggests that alternative, more practicable options are used to resolve the issues, for example, prescribers writing prescriptions for the SSP alternative. Also, that formulation changes should be permitted at the supervising pharmacist's professional discretion.

Proposal: *DHSC to resolve outstanding SSPs issues – to provide proper payment for more complex SSPs; and formulation changes to be permitted at the pharmacist's discretion and patient consent – relevant amendments to be included in the Human Medicines Regulations and NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.*

Ensuring contractor and staff wellbeing

NHSE has previously stated that it recognises the stress placed on NHS workers and that the safety, health and wellbeing of staff as a key priority. These statements of intent should be backed up with action, recognising other relevant considerations, including employers' responsibilities to staff and the General Pharmaceutical Council (GPhC) standards for registered pharmacies.

Proposal: *DHSC and NHSE to ensure contractor and staff wellbeing without the worry that to do so might breach NHS contractual requirements – to consider, for example, where staff are overwhelmed with workload, there may be a temporary need to decline to accept patients for Advanced services offered by the pharmacy; or where: one pharmacist is the Responsible Pharmacist (RP) for the entire week for a rural pharmacy, and there is no realistic opportunity to engage a locum, and the contractual opening hours cannot be managed safely by that RP, there may be a need for the pharmacy to close (not open during normal contractual opening hours) for an appropriate period of time each week.*

Note: The pharmaceutical regulations already provide that there is **no breach for an unplanned temporary closure for reasons beyond the contractor's control**, subject to certain actions by the contractor. Also, supplementary opening hours may be reduced with 5 weeks' notice to NHSE.

Supervision/Skill Mix and Original Pack Dispensing (OPD)

In 2019, DHSC and NHSE promised efficiencies as part of the five-year CCPF agreement. This included the Government agreeing to explore and implement greater use of OPD to support efficient automation and to propose legislative changes that would allow for better use of the skill mix in pharmacies and enable the clinical integration of pharmacists. In the Autumn of 2022, the promise was reiterated, but we still have yet to see further progress.

Proposal: *DHSC to progress appropriate changes to supervision/skill mix and OPD, which have the potential to deliver efficiencies that were promised in 2019, at the start of the 5-year deal and remain undelivered.*

Minor regulatory easements which collectively could have an impact

A number of other proposals have also been put forward:

1. No requirement to ask a patient to provide evidence of a prescription exemption or give advice to the patient/representative as to what checks the NHS may make, if no evidence is provided.
2. No health campaigns to be required in 2023/24.
3. Remove the requirement to produce a practice leaflet.

4. Remove the requirement to publicise Essential and Advanced services.
5. Pause all Healthy Living Pharmacy (HLP) requirements in 2023/24.
6. No NHSE determined national clinical audit for 2023/24.
7. No contractor, practice-based audit required in 2023/24.
8. No submission of an annual self-assessment of compliance with information governance (compliance with information governance requirements remains applicable) - i.e. no DSP Toolkit for 2023/24.
9. No quarterly verification of NHS website and DoS entries, where there are no changes to be made to the profiles.
10. Very limited CPAF – so no CPAF beyond the screening questionnaire – and no other questionnaires for the year 2023/24.
11. No requirement to submit an annual complaints report.
12. Notification of temporary closure beyond a contractor's control to be completion of amendments to the pharmacy's NHS website and DoS entries (rather than the current suggested notification form).
13. No patient signature to be required on a prescription or EPS token where the patient pays the NHS prescription charge, as long as the pharmacy holds a record of that payment (e.g. on the PMR). This change would remove the requirement for contractors to submit paid tokens to the NHSBSA.
14. Remove the requirement to endorse EPS prescriptions for specials with SP - these could be automatically identified by the NHSBSA by the product name.

If you have queries on this PSNC Briefing or you require more information, please contact info@psnc.org.uk.